DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 26, 2015

Genadyne Biotechnologies Incorporated
Mr. Chien-Ming Goh
Vice President
16 Midland Avenue
Hicksville, New York 11801

Re: K141961
Trade/Device Name: Spiro Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 23, 2015
Received: February 25, 2015

Dear Mr. Goh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141961

Device Name
Spiro Foam Dressing Kit

Indications for Use *(Describe)*
Genadyne Spiro Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious materials and tissue debris.

Spiral Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510k Summary

General Information **Date: July 10, 2014**

1.	**Applicant**	Genadyne Biotechnologies, Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.487.8787 (f) 516.977-8974
2.	**Contact Person**	Mr. Chien-Ming GOH (Andrew) Vice President Genadyne Biotechnologies Inc. 16 Midland Ave, Hicksville, NY 11801 (t) 516.217.0101 (f) 516.977.8974
3.	**Trade Name**	Genadyne Spiro Foam Dressing Kit (Ref: XF-SPMK1)
4.	**Common Name**	Foam Dressing
5.	**Classification Name**	Powered Suction Pump
6.	**Regulation Number**	21 CFR 878.4780
7.	**Product Code**	OMP
8.	**Class in which Device has been placed**	Class II
9.	**Panel**	General & Plastic Surgery
10.	**Reason for Premarket Notification**	New Device
11.	**Identification of Legally Marketed Device Which We Can Claim Substantial Equivalence (Predicate Device)**	A4-XLR8 Foam Dressing K092992
12.	**Brief Description of Device**	Gendayne Spiro Foam Dressing Kit is a single-use dressing is housed in a Tyvek/Mylar Peel Pouch.

13. **Indications for use [21 CFR 807.92(a)(5)]**

Genadyne Spiro Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious materials and tissue debris.

Spiro Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency Ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

14**. Technological Characteristics**

No.		Foam	Port Tubing	Film
1.	Materials Used:	Flexible Polyether and Polyester Polyurethane Foam	Silicone	Polyurethane
2.	Size:	104 +/- 1.5 cm uncoiled length x 1.9 +/- .3 cm width x 1.6 +/-0.15 cm height	31 inches	26 x 30 cm

Table of Comparison to Predicate Devices:

	Predicate	New
Parameters	Genadyne A4-XLR8 Foam Dressing	Genadyne Spiro Foam Dressing Kit
510(k) Number	K092992	
Indications for Use	Genadyne A4-XLR8 Foam Dressing Kits are intended to be used in conjunction with the Genadyne Wound Vacuum System to deliver negative pressure to the wound. Genadyne Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the	Genadyne Spiro Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may

	removal of excess exudates, infectious materials and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts	promote wound healing by the removal of excess exudates, infectious materials and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds Skin flap and grafts
Foam Dressing Material	Flexible Polyether and Polyester Polyurethane Foam	Flexible Polyether and Polyester Polyurethane Foam
Hydrophobic	Yes	Yes
Sizes:	7.5 cm X 10 cm x 3.3cm 12.5 cm x 18 cm x 3.3 cm 15 cm x 26 cm x 3.3 cm	104 +/- 1.5 cm uncoiled length x 1.9 +/- .3 cm width x 1.6 +/-0.15 cm height
For use with Negative Pressure Wound Therapy Systems	Yes	Yes
Sterile	Yes	Yes
Kit Content	Silicone Tubing Transparent Adhesive Film	Silicone Tubing Transparent Adhesive Film

15. **Non Clinical Tests**

XLR8 Spiro Dressing Kit	Biocompatibility tests were performed on the dressing kit in accordance to ISO 10993. Report can be found in 013_Attachment_D in the RTA submission.	In Report 13-02487-G1, the green foam dressing kit meets the requirements of the test as per ISO 10993-5, and is not considered to have a cytotoxic effect. In Report 13-02487-G2, the green foam dressing kit meets the requirements of the ISO 10993-10 guidelines. It did not show a significantly greater biological reaction than the sites injected with the control article. In Report 13-02487-G3, the green foam dressing kit displayed a Grade 1 sensitization rate and based on the scoring system of Kligman as per ISO 10993-10 guidelines, it is not considered significant and is classified as having a weak allergenic potential. In Report 13-02487-G4, the green foam dressing kit is considered non-pyrogenic and meets the requirements of the Pyrogen Test, as per ISO 10993-11 guidelines. In Report 13-02487-G5, the green foam kit did not induce a significantly greater biological reaction than the control extracts, when tested in Swiss Albino mice, therefore it is considered negative based on standards set by ISO 10993-11.

	Sterilization validation was performed in accordance to ISO 11135. Report can be found in 016_Attachment I in the original submission.	The sterilization activity confirms a 10^{-6} sterility assurance level (SAL), by utilizing the half-cycle overkill approach which demonstrated total inactivation of a 10^{-6} BI at half exposure time, on a four (4) pallet load of wound vacuum dressing sets.
	Stability test was performed and the report can be found in 015_Attachment H in the original submission.	In the stability test, we performed:- 1. Accelerated aging test 2. Peel test 3. Bubble test 4. Ship test 5. Package aerosol spore challenge test All test results shows that the packages met the requirements of the protocol for 2 year equivalent aging. No significant degradation of seal was observed, bubble test showed no leaks at any test points, microbial challenge shows good resistance and no significant degradation, and bubble test after ship test showed no leaks.
	Colorant test was performed on the blue and yellow colorant that makes the green foam. The report can be found in 015_Attachment F.	In Report 14-04232-N1, a test to determine the extractable amount of chemical compounds from sponsor test material was performed. In the test against metals, no elements above reporting limit were detected in any of the colorants except for sodium in Reactint Blue X3LV. However, sodium was also observed in the control solution (purified water) this presence of sodium cannot be unequivocally attributed to blue colorant. In the test against volatile organic compound (VOC), no VOC were observed in any of the colors nor samples. In the SVOC analysis of the purified water extract, no SVOC attributable to the test article were observed. No SVOC were observed in colorant solutions. In the target NVOC analysis of purified water extracts, no target-NVOC attributable to the test article were observed. No NVOC were observed in the colorant solutions. In the Non-Target NVOC in purified water extracts, no additional peaks were observed in the LC chromatogram of samples compared to the LC chromatogram of control.

16. **Conclusion & Determination of Substantial Equivalence**

Based on the information presented above, it is concluded that the Spiro Foam Dressing Kit is substantially equivalent to the predicate device.